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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,845	01/17/2002	Jesse M. Carter		2089

7590

10/15/2003

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EXAMINER

GAKH, YELENA G

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 10/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

elb3

Office Action Summary

Application No.

10/051,845

Applicant(s)

CARTER ET AL.

Examiner

Yelena G. Gakh, Ph.D.

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☒ Claim(s) 1-10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

1. No references accompanied IDS form 892; non-patent literature is not readily available to the examiner and therefore only patents were considered. NPL will be considered upon submission.

Claim Objections

2. Claims 1-10 are objected to because of the following informalities: the proper name for all "N,N,N,N-tetramethyl-" derivatives is "N,N,N',N'-tetramethyl-". Also, -" N,N,N',N'-tetramethyl-1,4-phenylenediamine" and "N,N,N',N'-tetramethylbenzidine", recited in claims 1-3 and 6 are the same compound. Appropriate corrections are required.

Claim Rejections - 35 USC § 103

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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5. **Claims 1-4 and 6-9** are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (US 5,759,860) in view of Cerwonka (US 3,619,187).

Smith teaches an "automated analysis method for detecting bacterial nitrite [oxidant] in urine" (Title) by "placing an aliquot of a urine sample in an automated analyzer first sampling cup, and a standard containing a known quantity of nitrite in a second cup; injecting known specified amounts of each sample from these cups into discrete cuvettes in the autoanalyzer, injecting at least one reagent composition in an aqueous medium containing a buffer, a compound to remove substances in the urine interfering with a colorimetric reaction, oxidized glutathione, and B-nicotinamide adenine dinucleotide phosphate or nicotinamide adenine dinucleotide and reading at a preprogrammed code in an automated analyzer at a preprogrammed wavelength to compare the patient's urine with the standard to determine quantitatively the presence of bacterial nitrite in the patient's urine" (Abstract). In one of the embodiments "the Bacterial Reductase/Nitrite/Indole reagent system" comprises "**a salt of iodide (Na, K, etc), N-(1-naphthyl) ethylenediamine, 1,2,3,4,-tetrahydroisoquinoline, hydrochloric acid, 4-nitrobenzenediazonium tetrafluoroborate, or another suitable azo dye that forms a complex with the diazonium salt, which can be measured spectrophotometrically at 540 nm**" (col. 6, lines 19-25).

Smith does not particularly disclose phenylamine chromogenic indicators of claim 1, such as N,N-diethylphenylene diamine and does not specify buffers.

Cerwonka teaches using substituted para-phenylene diamines, such as N,N-dimethyl- and N,N-diethyl-para-phenylene diamines in the presence of alpha-hydroxy carboxylic acids, including citric acid, as color couplers to give color reaction in the presence of oxidation agents.

The buffers of claim 9 are standard buffers.

It would have been obvious for anyone of ordinary skills in the art to slightly modify Smith's method by using N,N-diethylphenylene diamine taught by Cerwonka instead of N-(1-naphthyl)ethylene-diamine, because both these aromatic amines have similar chemical properties regarding their participation in the same coupling reaction which gives color products in the presence of oxidizing agent (nitrite), and to use any standard buffers to adjust pH to the optimal value.

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6. **Claims 5 and 10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (US 5,759,860) in view of the well known prior art, e.g. Morris et al. (US 5,173,434).

Smith does not particularly disclose N,N,N',N'-tetramethyl-1,4-phenylenediamine (N,N,N',N'-tetramethylbenzidine) as a phenylamine chromogenic indicator.

Morris discloses N,N,N',N'-tetramethyl-1,4-phenylenediamine (Wurster's reagent or Wurster's blue) as a well known redox indicator (indicator which changes its color upon oxidation with oxidizers) for detecting oxidizers in urine (col. 1, lines 50-55 and Example 3, col. 12, lines 28-44). Blue color has absorbance in the range of 400-450 nm, depending on the oxidants present in urine.

It would have been obvious for anyone of ordinary skill in the art to slightly modify Smith's method by using Wurster's blue disclosed by Morris as a redox indicator, and to optimize the conditions for detecting specific oxidants at 415 nm (blue region) in 0.25 N HCl with the time for developing color of 1 min. See *In re Aller*, 105 USPQ 233 (CCPA 1955) (the use of optimum amount of a known reactant is within the ambit of one skilled in the art); *In re Boesch*, 205 USPQ 215 (CCPA 1980) (the discovery of an optimum value of a known result effective variable without producing any new or unexpected results is within the skill of the routineer in the art).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (703) 306-5906. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Yelena G. Gakh

10/11/03

